

REMARKS

The Examiner is thanked for the due consideration given the application. This Amendment is being filed concurrently with a Request for Continued Examination. The specification has been amended to insert headings.

Claims 21-40 are pending in the application. Support for the amendments to claims 21 and 28 can be found in the specification at page 7, lines 8-11. Other claim amendments improve the language in a non-narrowing fashion.

No new matter is believed to be added to the application by this Amendment.

Claim Objections

Claims 35 and 37 have been objected to as containing informalities. The comments in the Official Action have been considered, and claims 35 and 37 have been amended accordingly.

Rejection Under 35 USC §112, Second Paragraph

Claims 21-27, 39 and 40 have been rejected under 35 USC §112, second paragraph. This rejection is respectfully traversed.

The Official Action asserts that the claims contain terms that render the claims indefinite. However, the claims have been amended to remove these terms or to use proper phrasing in the alternative.

The claims are thus clear, definite and have full antecedent basis.

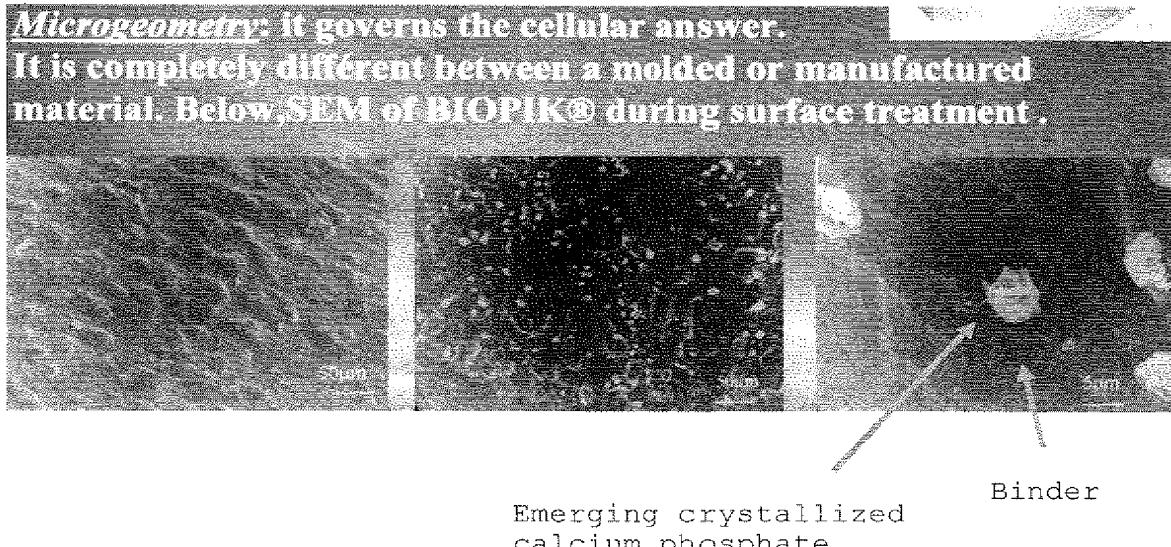
This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Rejections Based on COUGOULIC

Claims 21-24, 26, 27, 39 and 40 have been rejected under 35 USC §103(a) as being unpatentable over COUGOULIC (U.S. Patent 5,872,159) in view of STEINEMANN et al. (U.S. Patent 5,456,723). Claim 25 has been rejected under 35 USC §103(a) as being unpatentable over COUGOULIC in view of STEINEMANN et al., and further in view of ELLINGSEN et al. (U.S. Publication 2002/0111694). Claims 28-38 have been rejected under 35 USC §103(a) as being unpatentable over COUGOULIC in view of STEINEMANN et al., and further in view of MILLS et al. (U.S. Patent 6,482,584).

These rejections are respectfully traversed.

The present invention pertains to a material for medical or veterinary usage that is formed from calcium phosphate and polymer biocompatible binder. The surface of this material is provided with emerging crystallized calcium phosphate. The emerging crystallized calcium phosphate can be seen in the photomicrograph reproduced below.

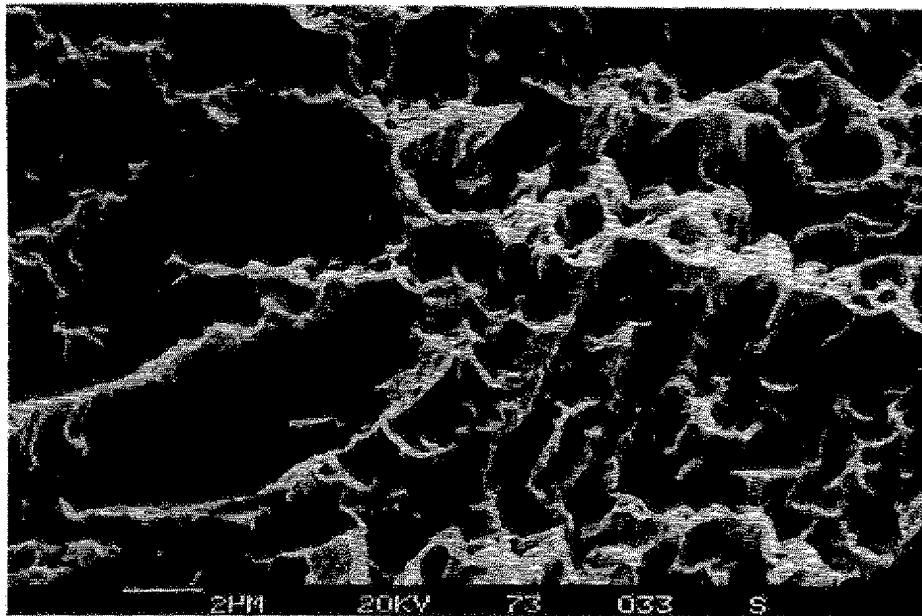


COUGOULIC pertains to a material in the form of a molded piecework, made of 65 to 90 % in weight of a biocompatible binder and 10 to 35 % in weight of at least one compound for adding calcium and phosphorus.

COUGOULIC fails to disclose or infer a provided with emerging crystallized calcium phosphate, such as is set forth in independent claims 21 and 28 of the present invention.

STEINEMANN et al. pertain to a metallic implant anchorable to bone tissue. STEINEMANN et al. disclose a implant, only made of metal, with a micro-roughness of 2 μm or less. This micro-roughness can be seen Figure 2 of the patent, which is reproduced below.

FIG. 2



Such micro-roughness can be readily produced by subjecting the contact surface to pickling in a reducing acid.

ELLINGSEN et al. is used for teachings pertaining to a binder. ELLINGSEN et al. fails to address the deficiencies of COUGOULIC in disclosing a surface with emerging crystallized calcium phosphate.

MILLS et al. disclose a method for perfusion of a porous implant, in particular of bone type, which achieves notably efficient cleaning of the implant. The process of MILLS et al. includes mainly in exposing the implant to increased and decreased pressure in combination with cleaning solution.

In contrast, the material of the invention distinguishes from the one described in COUGOULIC and the

secondary references, by the fact that it has a surface provided with emerging crystallized calcium phosphate.

Indeed, in practice, it has been discovered that the molded material described in COUGOULIC has a surface composed mainly of the biocompatible binder (which does not have such crystallized calcium phosphate). Moreover, the calcium phosphate integrated in the binder is not in a crystallized state.

On the other hand, the surface of the material, in accordance to the present invention, is interesting in that it confers some particularly efficient integration characteristics to the surrounding tissue, better than the ones of the material not having such emerging crystallized calcium phosphate.

In practice, after implantation into the bone, the surrounding tissues use and remove the emerging crystallized calcium phosphate, which create holes at the surface of the materiel then colonized by said tissues.

This phenomenon contributes to the optimal integration of the material into the surrounding tissues, as is set forth in the slide reproduced below.

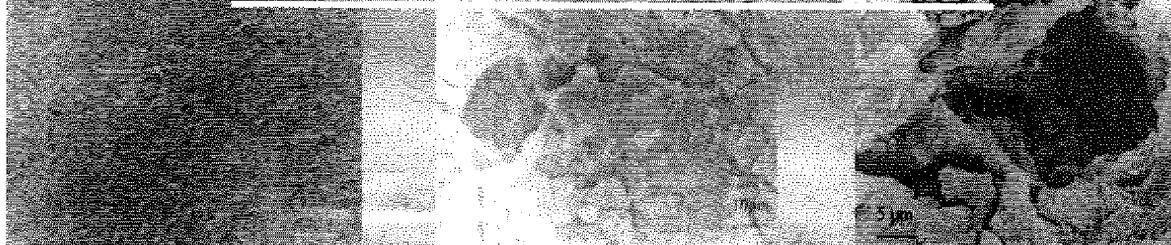
Surface quality after explantation

The cells recognize only the layer of pollution at the surface not the center of the material.

Our principle of treatment activates the surface of BIOPIK®, thanks to the cleaning surface which gets rid of any pollution.

So, after retrieval, and XPS study, we found that the biologic environment acts on the Biopik® and contributes to nitrogen supply on its surface with covalent links, or BIOPIK® never contains nitrogen before implantation.

Can't we speak of natural graft ?



The objective technical problem for one skill in the art would thus be to activate the surface and to optimize the integration characteristics in the surrounding tissue, of the molded material described in the closer prior art of COUGOULIC.

However, if one with skill in the art wishes to optimize the integration characteristics of the material described in COUGOULIC, he or she would not have any reason to activate the surface of the material by providing it with emerging crystallized calcium phosphate.

One skill in the art would not have any reason to use the teaching of document STEINEMANN et al., since it relates to a metallic implant. STEINEMANN et al. fails to relate to a material comprising calcium phosphate.

And STEINEMANN et al. fails to describe a way to activate the surface of such a material (particularly in making easier the access to a constituent compound of the material, here emerging crystallized calcium phosphate).

Even if one skill in the art has any surprising reason to use this teaching of STEINEMANN et al., he or she would thus be at the most motivated to activate the surface thanks only to a micro-roughness aspect/pattern.

However, this activated micro-roughness surface based on STEINEMANN would be totally different from the activated surface of the material according to independent claims 21 and 28, i.e., where the surface is provided with emerging crystallized calcium phosphate.

One skill in the art would not have any reason to use the teaching of MILLS et al., since this patent relates only to a porous implant, which is not the case of the material defined in independent claims 21 and 28, and to a method for perfusion said porous implant in order notably to sterile it.

Indeed, this document does not describe a way to activate the surface of a material.

MILLS et al. does not relate also to a material comprising calcium phosphate (particularly to make easier the access to a constitutive compound of the material, here emerging crystallized calcium phosphate).

Nevertheless, even if one skill in the art has any reason to use this teaching, he would not have any reason to develop a material having emerging crystallized calcium phosphate as set forth in independent claims 21 and 28.

One of skill would indeed be, at the most, motivated to implement increased/decreased pressure in combination with cleaning solution. But this treatment, or at least the general information of MILLS et al., would not be sufficient to obtain the material according to the present invention.

Further, regarding independent method claim 28, STEINEMANN et al. does not also relate to a material formed from calcium phosphate, and it does not describe a way to activate the surface of such a material (particularly in making easier the access to a constitutive compound of the material, here emerging crystallized calcium phosphate).

Even if one skill in the art has any surprising reason to use this teaching, he or she would thus be at the most motivated to implement a pickling treatment on the material.

However, because of the lack of the final autoclave sterilization, this single pickling treatment would not be sufficient to obtain the material according to base claim 28, i.e., where the surface is provided with emerging crystallized calcium phosphate.

Also, one of skill in the art would not also have any reason to use the teachings of MILLS et al., since it relates

only to a porous implant and to a method for perfusion said porous implant.

As mentioned above, MILLS et al. fail to describe a way to activate the surface of a material. This document also fails to relate to a material comprising calcium phosphate, particularly to make easier the access to a constitutive compound of the material, here emerging crystallized calcium phosphate.

Also, as discussed above, ELLINGSEN et al. is only used for teaching pertaining to a binder.

The above observations and graphics can be re-submitted in a Declaration, if the Examiner so desires.

One of ordinary skill and creativity would thus fail to produce a claimed embodiment of the present invention from a knowledge of COUGOULIC and the secondary references. A *prima facie* case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

CONCLUSION

The objections and rejections are believed to have overcome obviated or rendered moot, and no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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